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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,534	06/22/2005	Jun Mori	123680	1629

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,534	MORI ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 8-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 11/03/08 was filed after the mailing date of the Specification on 6/22/05. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-6 and 8-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/579,055. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to percutaneous formulations comprising either an aqueous base or rubber base and 0.1-30 percent by mass of 3-

methyl-1-phenyl-2-pyrazolin-5-one. The formulatiosn comprise an aquesou of rubber base, a water soluble polymer, a crosslinking agent, polyhydric alcohol and water. The instant claims recite specific polymers as defined by the instant specification as meeting each of these compositional components. The instant claims recite specific water soluble polymers such as polyacrylamide, polyethyene imine, carboxyvinyl polymers, starch acrylate, and starch. These polymers are recited in the Specification as useable water soluble polymers. The copending claims, though broader would be encompassed by the instant claims. Also, the copending claims recite a method of making the same percutaneous formulation. The only active step in the method is combining the ingredients together. The result of this method is the same percutaneous drug formulation comprising the same drug, water-soluble polymers, tackifiers, cross-linkers and polyhydric alcohol as the instant claims. It would have been obvious to use the method of making a percutaneous formulation as recited in the copending '055 patent in order to make the composition of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-6, and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Koide et al (JP 10-265373 hereafter '373) in view of Uchiumi et al (JP 10-279480 hereafter '480). The claims are drawn to a transdermal formulation comprising a drug, water-soluble polymer, crosslinking agent, a polyhydric alcohol and a mass of water.

The '373 patent discloses a tacky adhesive composition comprising a drug, water-soluble polymer, cross-linking agent a polyhydric alcohol and water (abstract). The water soluble polymers include rubber polymers such as polyacrylates [0013], and these polymers make up 1-15% [0014]. The formulation comprises crosslinking agents that make up from 0.1-10% of the formulation and include glycine [0017-0019]. The formulation comprises polyhydric alcohols such as ethylene glycol and propylene glycol that make up from 15-50% of the formulation [0020-0021]. The formulation further comprises tackifiers such as cellulosic resins, where the compounds are present in the formulation up to 15% [0020]. The water content of the formulation ranges from 40-70% [0038]. The drugs range from 0.001-10% of the drug formulation [0031] and can range from anti-inflammatory agents to muscle relaxants and vitamins [0030-0031]. The tacky formulation is applied to a film or substrate and applied to the skin [0022]. The tacky topical formulation, while disclosing a wide range of active agents is

silent to the specific active agent of the instant claims. The inclusion of this compound is well known in the art as seen in the '480 patent.

Regarding whether the substrate and the base layer are laminated together, it is the position of the Examiner that such limitations do not carry patentable weight since they are product-by-process limitations. The prior art discloses a structurally complete composition and regardless of the process by which the components are combine the combination should have the same properties as the instant claimed combination. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Regarding the future intended use of the adhesive preparation, it is the position of the Examiner that such limitations are met inherently by the prior art since the prior art discloses a structurally complete formulation identical to that of the instant claims. The adhesive preparations comprise the same components and as such would be used for the same purposes inherently.

The '480 patent discloses a topical drug formulation comprising 3-methyl-1-phenyl-2-pyrazolin-5-one in combination with well known excipients (abstract). The formulation comprises water soluble polymers such as polyvinylpyrrolidone, alcohols such as ethanol, and a mass of water [0013-0014]. The reference is silent to the percentage of the formulation however the compound comprises up to 50% of the composition (abstract). It would have been obvious to

combine the compound of the '480 patent into the topical formulation of the '373 patent since they both provide similar water soluble topical formulations.

It would have been obvious to combine the compound of the '480 patent into the topical preparation of the '373 patent in order to improve the transdermal delivery of the '480 compound. One of ordinary skill in the art would have been motivate to make this combination with an expected result of stable percutaneous formulation useful in treating skin tissue disturbances.

Response to Arguments

Applicant's arguments filed 2/13/09 have been fully considered but they are not persuasive. Applicant argues that none of the prior art patent disclose, *inter alia* the claimed aqueous of rubber based formulation of the claims in the recited percentages of the instant claims based on mass.

Regarding this argument it remains the position of the Examiner that the combination of the Koide and Uchiumi patents obviates in the instant claims. The Koide patent discloses a percutaneous absorption formulation comprising a wide variety of possible agents in a concentration up to 10% of the total mass. The formulation can be aqueous based or rubber based. The formulation comprises the same water soluble polymers of the instant claims and further excipients including crosslinking and tackifying agents. The patent discloses a wide variety of active agents including psychotropic, antibiotic, and skin treatment compounds. It would have been obvious to simply substitute any known compound into the formulation for percutaneous administration. Applicant argues that the concentrations of the desired active agent is not disclosed or suggested by the prior art, specifically that the Uchiumi patent doe snot

disclose the concentration. However Applicant is reminded that the Uchiumi patent is merely used as a supporting reference to establish that topical and percutaneous formulations of the 3-methyl-1-phenyl-2-pyrazolin-5, not an anticipatory reference disclosing each and every element of the instant claims. The formulation including polymers and percentages is taught by the Koide patent. The Koide patent also suggests a wide range of active agents, some similar to the active compound of the Uchiumi, and at an appropriate percentage (up to 10%) for percutaneous absorption. It would have been obvious to simply substitute the compound of the Uchiuimi patent into the formulation of the Koide patent since the patent disclose similar compounds being delivered with the carrier formulation. For these reasons the claims remain obvious.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618